K121557

TABLE 4 510K **SUMMARY**

JUL 25 2012

1. Date the summary was prepared: July 18, 2012

2. Submitter's name: Guangzhou Wondfo Biotech Co., Ltd.
   Address: South China University of Technology
   Guangzhou, P.R. China 510641
   Phone: 012-86-20-32296069

   Name of contact person: Joe Shia
   LSI International Inc.
   504 East Diamond Ave.,
   Suite F Gaithersburg, MD 20878
   Telephone: 240-505-7880
   Fax: 301-916-6213

3. Name of the device: Wondfo Cannabinoids Urine Test
   Wondfo Propoxyphene Urine Test
   Common or usual name: Cannabinoids Urine Test
   Propoxyphene Urine Test
   Trade or proprietary name: Wondfo Cannabinoids Urine Test
   Wondfo Propoxyphene Urine Test

Classification: All are Class □ medical devices with the following various product codes with Code of Federal Regulation references:

Product Code	CFR #
LDJ	21 CFR 862.3870
JXN	21 CFR 862.3700

4. The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:
   1. Acon Laboratories, Inc. ACON One Step Drug Screen Test, K020771.
   2. Acon Laboratories, Inc. ACON One Step Propoxyphene Test Device and Test Strip, K040445

5. Description of the device:

   Assay Principle: Immunochromatograph assay for Cannabinoids and Propoxyphene Urine Test using a lateral flow, one step system for the qualitative detection of 11-nor-Δ9-THC-9-COOH and d-propoxyphene (target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate from mouse against drug with gold chloride and fixed drug-protein conjugate and anti-mouse IgG polyclonal antibody in membrane.

6. Intended use of the device:

   Wondfo Cannabinoids Urine Test and Wondfo Propoxyphene Urine Test are intended for the qualitative determination of 11-nor-Δ9-THC-9-COOH and d-propoxyphene (target analyte) at the specific cut-off concentration in human urine. For in vitro diagnostic use only. Wondfo Propoxyphene Urine Test is only intended for prescription use. Wondfo Cannabinoids Urine Test is intended for over-the-counter and prescription use.

7. Comparison to the predicate device

A summary comparison of features of the Wondfo Cannabinoids Urine Test and the Wondfo Propoxyphene Urine Test and the predicate devices is provided in the Table 1 & Table 2.

Table 1: Features Comparison of the Wondfo Cannabinoids Urine Test and the Predicate Device

Item	Device	Predicate - K020771
Indication(s) for Use	For the qualitative determination of Cannabinoids in human urine.	Same
Calibrator	11-nor-Δ9-THC-9-COOH	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut Off Values	50 ng/mL	Same
Configurations	Cup, Dip Card	Card, Card with Integrated Cup
Intended Use	OTC Use & Prescription Use	Prescription Use

Table 2: Features Comparison of the Wondfo Propoxyphene Urine Test and the Predicate Device

Item	Device	Predicate - K040445
Indication(s) for Use	For the qualitative determination of d-Propoxyphene in human urine.	Same
Calibrator	d-propoxyphene	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Specimen Type	Human Urine	Same
Cut Off Values	300 ng/ml	Same
Configurations	Cup, Dip Card	Strip, device
Intended Use	Prescription Use	Same

The Wondfo Cannabinoids Urine Test and Wondfo Propoxyphene Urine Test have similar technological characteristics and performance to the predicates. They are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Guangzhou Wondfo Biotech Co., Ltd
c/o Joe Shia
c/o LSI International Inc.
504 East Diamond Ave.
Suite F
Gaithersburg, MD 20877

JUL 25 2012

Re: k121557
Trade Name: Wondfo Cannabinoids Urine Test
Wondfo Propoxyphene Urine Test
Regulation Number: 21 CFR §862.3870
Regulation Name: Cannabinoid Test System
Regulatory Class: Class II
Product Codes: LDJ, JXN
Dated: June 26, 2012
Received: July 16, 2012

Dear Mr Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121557

Device Name: Wondfo Propoxyphene Urine Test

Indications for Use:

Wondfo Propoxyphene Urine Test is an immunochromatographic assay for the qualitative determination of d-Propoxyphene in human urine at a cutoff concentration of 300 ng/mL. The test is available in a dip card format and a cup format. This product is only intended for prescription use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a conformed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use ___X___ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use_____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121557

Indications for Use Form

510(k) Number (*if known*): K121557

Device Name: Wondfo Cannabinoids Urine Test

Indications for Use:

Wondfo Cannabinoids Urine Test is an immunochromatographic assay for the qualitative determination of 11-nor-Δ9-THC-9-COOH (major metabolite of Cannabinoids) in human urine at a cutoff concentration of 50 ng/mL. The test is available in a dip card format and a cup format. It is intended for prescription use and over the counter use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a conformed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use___X___. (21 CFR Part 801 Subpart C)

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